Testimony of Ashley C. Gould, General Counsel, 23andMe, Inc.
"Direct-To-Consumer Genetic Testing and Consequences to the Public Health"
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations, U.S. House of Representatives
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Chairman Stupak, Ranking Member Burgess, and Members of the Subcommittee: Good morning, and thank you for inviting me to discuss this important issue.

My name is Ashley Gould, and I am the General Counsel of 23andMe, Inc., a leading personal genetics company dedicated to research and helping individuals understand their own genetic information through DNA analysis technologies and web-based interactive tools. I ask that the full written testimony be submitted for the record.

I. Overview

Direct-to-consumer (DTC) genetic testing leverages the findings from the Human Genome Project. Genetic testing has the potential to allow individuals to access their genetic information – the building blocks of their genome. Customers empowered with this information have made lifestyle changes aimed at reducing their risks of developing disease and have provided information to their doctors to aid in diagnosis and treatment. These actions have improved and even saved lives. Consumers can only be helped if such services operate at the highest levels of both science and ethics. We thus greatly appreciate the Subcommittee's interest in this increasingly important area of personal health, and we support sensible U.S. Food and Drug Administration (FDA) regulation of genetic and other forms of direct-to-consumer testing.

Before explaining our DTC genetic testing services more specifically, we would like to explain that 23andMe operates pursuant to the following core beliefs and facts:

A. Consumers have a fundamental right to access their personal genetic information;

B. 23andMe takes a holistic approach in providing genetic information to customers. Customers are provided with as much scientifically-sound information as is available so that they can learn as much as possible;

C. 23andMe provides a platform for customers to participate in the research process, so that we can all learn more about genetics and diseases;

D. Genomics has reached the stage where 23andMe can provide personal genetic information to consumers in a cost-effective manner. 23andMe relies on experts, both internally and on an outside board of prominent science advisors, to provide its services based firmly on peer-reviewed science;

E. 23andMe provides genetic testing results to consumers in a secure, confidential, and privacy-protected environment;

F. 23andMe encourages our customers to consult with medical professionals before taking any medical action based on DTC results; and

G. 23andMe supports federal standard-setting or other sensible regulatory activities to protect consumers and increase transparency.

II. Background

23andMe met with the FDA even before we launched our service, explained the full scope of our proposed services, and were encouraged to continue with our service by the then-FDA commissioner. Even while we have not been actively regulated by the FDA, we have embraced the scientific standards normally applied in a regulated environment. Based on FDA and Clinical Laboratory Improvement Amendments (CLIA) standards, we have created a sophisticated, high-quality testing process.

To process and analyze our customers' saliva samples, 23andMe contracts with the National Genetics Institute (NGI) – a wholly owned subsidiary of the Laboratory Corporation of America. NGI is a CLIA Program-certified laboratory that provides advanced clinical genetics testing services for blood screening, medical testing, and clinical research. Licensed as a clinical laboratory provider by both state and federal agencies, NGI participates in a number of approved quality control programs, and holds active Biologics Licenses from the FDA for screening of plasma for blood-borne infectious agents. It also provides advanced genetic testing services to physicians, hospitals, and clinics, and has supported numerous pharmaceutical and biotechnology companies in the clinical development of new infectious disease and oncology therapies. (See Attachment A). We believe that NGI complies with the highest professional, regulatory, and corporate quality-assurance standards.

NGI processes customer saliva samples using a chip that analyzes nearly 600,000 data points – the building blocks of the genome that I referred to above. After NGI completes the analysis, the collected data for each sample is encrypted using leading technologies to protect privacy, and sent electronically to 23andMe, which then uploads the data to the customer's individual account. 23andMe then notifies its customers that their data are loaded and ready for viewing.

Throughout this process, 23andMe provides strong safeguards for our customers' privacy and confidentiality. We have invested in a sophisticated technical environment for the storage and security of customer data and have had independent security audits to verify that security is state-of-the-art. As a part of our Terms of Service, we educate customers about our service and what will be provided – including how to use their information, how their information is protected, and the scientific limitations. During account registration, each customer is required to focus his or her attention on relevant highlighted sections of our Terms of Service and agree to them. In addition, we have

consulted on privacy issues with leading experts in the field, including the Electronic Frontier Foundation, to adopt the highest standards and best practices for storing and safeguarding our customer data.

Equally important, 23andMe grounds its service in five core elements: (A) informed consent; (B) educating customers about personal considerations they should take into account when using our service; (C) educating customers about the science and methodologies behind our service; (D) updating customers with new information as the science advances; and (E) emphasizing that customers should consult with health care professionals before taking any medically-related actions based on our reports.

A. Informed Consent and Privacy

We require informed consent from customers before they use our services so that they understand our permitted uses of their data and what our reports indicate – both the information and its limitations. We take extra precautions with certain reports. For example, we ask customers to be certain they want to know potentially significant information, and insert interstitial pages that must be clicked through before viewing our Parkinson's and BRCA reports. This way, a customer has the chance to reflect before making an affirmative choice to view his or her data.

No individual customer information is ever disclosed to third-parties without explicit consent (unless required by law). In addition, we recently introduced an institutional review board-approved consent document, which allows customers to decide if they would like to participate in research intended for peer-reviewed publication. In such instances, customer information will only ever be provided on an aggregate basis. As a constant reminder to our customers, our consent document, terms of service, and privacy statement are all available for review via links on every page of our website.

B. Education About Customers' Personal Considerations

Our customers come to our service because they are motivated to learn about their genes. Customers are not compelled to learn any information, and we designed the web site to allow customers to choose to learn the information that interests them. Our Terms of Service page clearly states that information customers learn could cause distress. Specifically, we disclose at length the following risks and considerations:

- "Once you obtain your Genetic Information, the knowledge is irrevocable;"
- "You may learn information about yourself that you do not anticipate;"
- "The laboratory may not be able to process your sample, and the laboratory process may result in errors;"
- "You should not change your health behaviors solely on the basis of information from 23andMe;"
- "Genetic research is not comprehensive;"

- "Genetic Information you share with others could be used against your interests;" and
- "23andMe Services are for research, informational, and educational use only. We do not provide medical advice."

For a complete and fully described list of disclosed risks and considerations, please see our Terms of Service. (See Attachment B). In addition, our public website contains a section addressing considerations before using our service or engaging in genetic testing. (See Attachment C).

C. Education and Transparency About the Science and Our Methodologies

We provide extensive information to our customers so they understand that the data we provide can change as new scientific studies are completed. We also explain the technology, algorithms, and methodology used to process and analyze their DNA. We have white papers readily accessible on our website that detail our inclusion criteria procedures and algorithms. In addition, for each trait, condition, or disease association we test, we explain whether the result is based on established research – meaning that the topic meets 23andMe's criteria for findings that are very likely to reflect real effects. The scientific community has largely reached consensus on these topics. We also explain whether the result is based on preliminary research – meaning that these studies still need to be confirmed by the scientific community. It also includes topics where there may be contradictory evidence. The results of these studies are not conclusive. We report associations based on preliminary research so that our customers know the most current information about what their genome says, but we provide the customers with contextual information so they know the research is preliminary.

When a customer receives his or her results related to a disease association, the customer receives the risk prediction in context of the average person's risk versus the risk for a customer with his or her genetic variations. We also educate our customers about the importance of the environment and other factors that also may influence their risk of disease. Disease is not determined by the genome alone. We provide extensive information about the condition and next steps, including encouraging customers to discuss their results with their physicians and to consult genetic counselors.

D. Updates on Changing Data

We are committed to keeping our customers educated on new scientific advances. After customers receive their initial results, we update them on new scientific findings. As new scientific studies uncover new information that changes our understanding of the genome and its meaning, we tell our customers how this new information changes their results. We believe customers have a right to be updated when advances in science change our understanding of their genomes, so we do not cut off our customers after one look – or a year of looks – at their information.

E. Emphasis on Physician and Genetic Counseling Support If Customers Have Questions

As stated, if customers have questions, we recommend that they should coordinate the receipt of their information with physicians or a genetic counselor. We do not offer genetic counseling services directly and in fact believe it is important for counselors to be independent of the company. We have provided links to such services previously and since early June 2010, we have offered our customers a referral to Informed Medical Decisions, Inc. (InformedDNA), an independent provider of genetic counseling services staffed by certified genetic counselors. These genetic counselors are trained professionals, who have additional training about the services and results that 23andMe provides.

To be clear, there is no financial relationship between 23andMe and InformedDNA. However, we do provide InformedDNA with background information about 23andMe's test offerings so that InformedDNA's genetic counselors will be prepared to discuss the tests we offer our customers. This service is optional for 23andMe customers, and customers who choose InformedDNA for genetic counseling services pay InformedDNA directly.

23andMe partnered with InformedDNA because it is the largest independent network of genetic counselors and is the only national provider whose services are a covered benefit for most individuals with commercial health insurance. (See Attachment D).

III. Concerns About DTC Genetic Testing

We recognize that there are concerns about customers having direct access to genetic testing, including the risk that individuals might make poor choices based on their results, and consistency of results among the different companies in this sector. We take those concerns extremely seriously.

A. Genetic Concerns

The best way to avoid poor choices is to have educated customers. Here are some of the things we are doing to educate customers: We have created educational videos that are on our public website (these have over 140,000 views on Youtube and are used by schools for genetic education). Our health reports have extensive information including description of the underlying scientific literature upon which reports are based, citations to these studies, the interplay between genes and the environment, and technical information and additional resources for those who are interested. We also educate the broader community. We have offered free genotyping to hundreds of physicians so they can learn about their data and understand their patients' needs, we are involved in medical school programs to further genetics understanding, and we are involved in numerous third-party research studies – some of which are described below.

With respect to concerns about people making poor choices, there is excellent scientific research being conducted about the impact and utility of DTC genetic testing. For example, the National Human Genome Research Institute and the National Cancer Institute of NIH, along with the Group Health Cooperative in Seattle and the Henry Ford Health System in Detroit, launched the "Multiplex Initiative" in May 2007 to study 2,000 people in Detroit who were offered a multiplex genetic test for eight common conditions. This study has shown that consumers understand that both genes and environment contribute to disease risk. As part of this research, researchers found that "[i]ndividuals who present to health care providers with online genetics information may be among the most motivated to take steps toward healthier lifestyles. These motives might be leveraged by health care providers to promote positive health outcomes." There is more to come, and it will educate all of us about what the actual issues might be and how to address them.

We want to better understand these issues ourselves, and to that end, 23andMe has worked with the Genetics and Public Policy Center at Johns Hopkins University to conduct an independent study of how 23andMe customers understand and use their results. We expect these results to be released later this summer, and we will keep you informed about them. We are also working on a related study with Stanford University.

23andMe has over 50,000 customers, and through monitoring community feedback, we are confident that DTC genetic testing has a positive impact on customers' lives.

B. The June 2010 Sample Mix-Up

Regarding concerns about accuracy and reliability, let me briefly address the reported June 2010 incident in which customers received results belonging to other people. A single human error by a certified technician at our contracted laboratory caused this incident. The technician accidentally and wrongly inverted a plate by 180 degrees, causing valid results for plate samples to be matched with the wrong person's name. This mismatching error at the laboratory led to 23andMe's receipt of mismatched results that were then transmitted to customers, affecting eighty-seven customers in all.

23andMe responded to the problem as soon as we learned of it from our community by notifying customers and removing the mismatched results in less than 24 hours. We were then able to give the customers their correct results within six days. While 23andMe regrets the error and takes the incident seriously, the company rapidly resolved it. Since the incident, both 23andMe and our laboratory have further strengthened our quality control systems to prevent such problems. The laboratory error that occurred here could have happened in any laboratory for any genetic tests coming from any hospital, doctor's office, or other laboratory client – it was not a problem uniquely related to 23andMe samples or DTC services to any extent. (See Attachment E).

C. Standards Setting

We fully appreciate the concerns that different companies can return different risk predictions, which can happen even when the tests are accurate. There are several scientific reasons for differences: companies employ slightly different criteria for the inclusion of disease-associated markers in their reports; new associations between genetic markers and diseases are being discovered at a rate faster than companies' development cycles; and companies test for an imperfectly overlapping set of genetic variants for reasons including the ability of different genotyping technologies to assay certain variants. We have asked NIH and FDA to help on this point. In addition, the industry is already looking to other reputable, independent entities that could take up this challenge, such as NIST, an independent standard setting entity.

IV. How DTC Genetic Testing and 23andMe Helps Consumers Improve Their Lives

Over the past decade, scientists have discovered that an increasing number of diseases can be linked to variations in an individual's DNA. These discoveries have launched the revolution in personal health, empowering individuals as never before to manage their personal health before they get sick. Thanks to such advances, we now understand that each of us is born with genetic predispositions for developing diseases.

In some cases, this information can truly save a life. A striking example is that of Kirk Citron. Kirk found out from 23andMe that he had about three times the normal risk for venous thromboembolism – something he never would have suspected. Knowing this information, Kirk did a little digging and found out his father's father had a blood clotting condition that had him on blood thinners for the last 20 years of his life. A few weeks later, Kirk tore his ACL and was told he needed to have knee surgery (which is one of the risk factors for blood clots).

Kirk went to his primary doctor and his orthopedist and told them he was worried about the risk, given his family history and his DNA test. Both doctors were somewhat dismissive of Kirk's concerns, but Kirk was insistent enough that they agreed to change the post-surgery protocol to give Kirk five days of blood thinner.

Kirk had the surgery and had the five days of blood thinner. Five days later, he suddenly felt short of breath. Kirk saw his doctor and was immediately admitted to the hospital – he had experienced a pulmonary embolism – a blood clot that traveled to his lung.

In discussing it afterwards, Kirk's doctor said two things: first, the fact that Kirk had been on the blood thinner for five days almost certainly meant that the attack was much less severe than it might have been (it could have been fatal). Second, having the information ahead of time allowed Kirk's doctor to make the diagnosis much faster than otherwise would have been the case. Once Kirk was in the hospital, and on a new round of blood thinners, he was out of danger, and now is home and doing just fine.

Our tests also detect genetic variations that have been linked with heart attacks, Crohn's Disease, macular degeneration, Parkinson's disease, Type 2 diabetes, and many others. As scientists continue to make breakthroughs, the number of diseases we can test for will only increase. Because new, reliable studies are being published weekly, even daily, we are regularly adding traits, diseases, and conditions to our testing. As we do so, we educate our customers on these latest scientific discoveries as they happen, but we only link them to our customers' personal data after we determine that they meet our standards of reliability.

23andMe's DTC service is consistent with the FDA's long history of approving at-home, over-the-counter tests for HIV, hepatitis, and fecal blood (which might be caused by colon cancer). In addition, FDA already permits customers to have direct access to tests for potentially less worrisome conditions, such as high cholesterol and pregnancy. As the FDA explains on its website, these tests help consumers "detect possible health conditions when [they] have no symptoms, so [they] can get early treatment and lower [their] chance of developing later complications ... [and] detect specific conditions when there are no signs so that [they] can take immediate action." (See Attachment F). Although the results of the FDA-approved, over-the-counter tests may lead to customers receiving potentially distressing information, the FDA has permitted consumers to have direct access to these tests. Our tests are even less worrisome, as they do not diagnose a disease but rather only provide more limited data.

V. How DTC Genetic Testing and 23andMe Help Develop and Accelerate Medical Research

Besides the direct consequences of genetic testing on healthcare, 23andMe is also strongly rooted in the development of innovative solutions for accelerating medical research. One of the unique features of 23andMe's DTC genotyping service is the company's focus on 23andWe, a community-centered research effort in which consumers are encouraged to contribute to medical science by answering surveys.

To date, through 23andWe surveys, 23andMe has amassed one of the largest databases of genetic and health information in existence. This database includes over 50,000 customers, of whom more than half have participated in at least one survey, and of whom roughly 10% have participated in at least 20 surveys in total. Our customers have answered over 10 million research questions. Last month, we published our first paper describing the results of a number of replications and several novel findings based on our customer data in the open access, peer-reviewed journal PLoS Genetics, and many more publications covering novel associations with more serious medical conditions are on the way.

We believe that this model of research has the potential to transform research in this field in two specific ways. First, unlike most research studies to date where the primary source of funding has been a government agency such as the NIH, our research model has been primarily driven by consumer interest. Second, our active cohort of

engaged customers has enabled us to pursue research into over 600 health conditions simultaneously, in contrast to traditional approach of funding a genotyping study for a single health condition at a time. This allows research to proceed at a much faster pace than possible in more traditional settings. For example, in March 2009, we began a project to study the genetics of Parkinson's disease. In less than a year, we were able to assemble a database of nearly 4,000 genotyped patients with Parkinson's disease, which enabled us to replicate previous findings as well as to discover a number of novel associations that had not previously been reported in the scientific literature. These novel associations are not yet reported to our customers because they have not yet been published in a peer-reviewed journal, which is one of our standards for inclusion.

Because we have such a large research database and engaged customers, we are able to assess the clinical significance of genome associations. We are in a unique position to tell our customers, and the community, how clinically significant this information is.

VI. 23andMe Supports a Strengthened Regulatory Framework for DTC Genetic Testing

23andMe has been working with federal authorities – and looks forward to continuing to work with them – on improving the regulatory framework for all diagnostic testing, including genetic testing. These are complicated issues, as evidenced by the fact that FDA just held a two-day meeting this week and heard from numerous medical, laboratory, academic, and industry groups about how to change the regulation of laboratory testing. We have met with the FDA several times and have had discussions with them on how they might regulate this new industry that does not fit squarely into any existing regulatory paradigm. We have also engaged with other officials at the U.S. Department of Health and Human Services and NIH.

We have been working on a proposed framework that we will present to the FDA tomorrow. This framework takes into account rapid technological innovation, and will ensure the analytical and clinical validity of all laboratory tests. We hope that the framework will lead to a scalable regulatory system for the FDA to adopt.

VII. Conclusion

Thank you again, Chairman Stupak, Ranking Member Burgess, and Members of the Subcommittee for giving me the opportunity to speak with you today and for your work on these issues.

Attachment A

National Genetics Institute

HOME COMPANY TESTING SERVICES LIBRARY CONTACT

Testing Services Overview

National Genetics Institute (NGI) provides advanced clinical genetics testing services for blood screening, medical testing, and clinical research. The company offers industry leading assays for human immunodeficiency virus (HIV), hepatitis A, B, and C (HAV, HBV, and HCV) viruses and other infectious agents and has pioneered robust, sensitive, and high throughput methods for pooled specimen nucleic acid testing.

NGI is a leading provider of nucleic acid screening services to the global biotechnology industry and screens millions of plasma donations a year for blood borne infectious agents (Screening Services). The company also provides its advanced genetic testing services to physicians, hospitals, and clinics (Medical Testing) and has supported numerous pharmaceutical and biotechnology companies in the clinical development of new infectious disease and oncology therapies (Clinical Research Services).

NGI is licensed as a clinical laboratory provider by both state and federal agencies, participates in a number of approved quality control programs, and holds active Biologics Licenses from the US Food and Drug Administration (FDA) for screening of plasma for blood borne infectious agents.

Test Menu

NGI offers a range of advanced genetics assays. Select a specific test below to obtain additional test information.

Please select one...

LabCorp

Attachment B

terms of service

1. Definitions

- **"23andMe"** means 23andMe, Inc., whose principal place of business is at 1390 Shorebird Way, Mountain View, CA 94043.
- **"23andWe Research"** means scientific research that 23andMe performs with the intent to publish in a peer-reviewed scientific journal. 23andWe Research only uses Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document. 23andWe Research activities do not include R&D.
- **"R&D"** means research and development activities performed by 23andMe on user data. These activities may include, among other things, improving our Services and/or offering new products or services to you; performing quality control activities; conducting data analysis that may lead to and/or include commercialization with a third party.
- **"Service"** or **"Services** means 23andMe's products, software, services, and website (including but not limited to text, graphics, images, and other material and information) as accessed from time to time by the user, regardless if the use is in connection with an account or not.
- **"Personal Information"** is information that can be used to identify you, either alone or in combination with other information. 23andMe collects and stores the following types of Personal Information:
  - **"Registration Information"** is the information you provide about yourself when registering for and/or purchasing our Services (e.g. name, email, address, user ID and password, and payment information).
  - **"Genetic Information"** is information regarding your genotype (e.g. the As, Ts, Cs, and Gs at particular locations in your genome), generated through processing of your saliva by 23andMe or by its contractors, successors, and assignees; or otherwise processed by and/or contributed to 23andMe.
  - **"Self-Reported Information"** is all information about yourself, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account. Self-Reported Information is included in 23andWe Research only if it has been indicated for 23andWe Research use on the website and if you have given consent as described in the applicable Consent Document.
  - **"User Content"** is all information, data, text, software, music, audio, photographs, graphics, video, messages, or other materials - *other than* Genetic Information and Self-Reported Information-generated by users of 23andMe Services and transmitted, whether publicly or privately, to or through 23andMe.
  - **"Web Behavior Information"** is information on how you use the 23andMe website (e.g. browser type, domains, page views) collected through log files, cookies, and web beacon technology.
- **"Aggregated Genetic and Self-Reported Information"** is Genetic and Self-Reported Information that has been stripped of Registration Information and combined with data from a number of other users sufficient to minimize the possibility of exposing individual-level information while still providing scientific evidence.

2. Acceptance of Terms

Your use of 23andMe's Services (excluding any services provided by 23andMe under a separate agreement) is subject to the terms of the legal agreement between you and 23andMe set forth in these Terms of Service (**"TOS"**). Except as specified herein, these TOS apply to any use of the Services, including but not limited to a) submitting a saliva sample for DNA extraction and processing, b) uploading a digital version of your Genetic Information and interacting with it on the 23andMe website, and/or c) creating and using a free 23andMe account without providing your saliva sample or Genetic Information. In order to use the Services, you must first agree to the TOS. You may not use the Services if you do not accept the TOS. You can accept the TOS by (1) clicking to accept or agree to the TOS, where this option is made available to you by 23andMe for any Service; or by (2) actually using the Services. In this case, you acknowledge and agree that 23andMe will treat your use of the Services as acceptance of the TOS from that point onwards. In addition, when using particular 23andMe Services, you shall be subject to any guidelines or rules applicable to such services that may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into the TOS. 23andMe also may offer other services from time to time that are governed by different terms of service.

3. Prerequisites

a. Whether you submit your own saliva sample, a saliva sample for anyone for whom you have legal authority to agree, or otherwise provide your own Genetic Information, you may not use the Services and may not accept the TOS if (1) you are not of legal age to form a binding contract with 23andMe, or (2) you are a person barred from receiving the Services under the laws of the jurisdiction in which you are resident or from which you use the Services.
b. In addition to the conditions above, if you contribute or otherwise provide your own Genetic Information, you must be eighteen (18) years of age or older to agree to these TOS on behalf of yourself or those for whom you have legal authority to agree.
c. If your use of the Services includes creating a 23andMe account, without submitting a saliva sample or otherwise providing Genetic Information, you must be thirteen (13) years of age or older to use the Services and accept the TOS.

4. Description of the Services

The Services include access to the 23andMe public website and personal genotyping services, including the collection and analysis of your saliva sample. Unless explicitly stated otherwise, each new feature that augments or enhances the current Service shall be subject to the TOS. You acknowledge and agree that the Services are provided "AS-IS" and are based on the current state of the art of genetic research and technology in use by 23andMe at the time of the purchase or viewing. As research progresses and scientific knowledge and technology evolve, 23andMe is constantly innovating in order to provide the best possible experience for its users. You acknowledge and agree that the

form and nature of the Services which 23andMe provides may change from time to time without prior notice to you. As part of this continuing innovation, you acknowledge and agree that 23andMe may stop (permanently or temporarily) providing some Services (or any features within the Services) to you or to users generally at 23andMe's sole discretion, without prior notice to you. You may stop using the Services at any time. You do not need to specifically inform 23andMe when you stop using the Services unless you are requesting closure of your account. 23andMe assumes no responsibility for the use of Services outside the terms of this TOS or other applicable terms.

In order to use the Services, you must obtain Internet access, either directly or through devices that access web-based content, and pay any service fees associated with such access. You are solely responsible for paying such fees. In addition, you must provide all equipment necessary to make such Internet connection, including a computer and modem or other access device. You are solely responsible for providing such equipment. You acknowledge and agree that while 23andMe may not currently have set a fixed upper limit on the number of transmissions you may send or receive through the Services or on the amount of storage space used for the provision of any Service, such fixed upper limits may be set by 23andMe at any time, at 23andMe's discretion.

5. Risks and Considerations Regarding 23andMe Services

Once you obtain your Genetic Information, the knowledge is irrevocable. You should not assume that any information we may be able to provide to you, whether now or as genetic research advances, will be welcome or positive. You should also understand that as research advances, in order for you to assess the meaning of your DNA in the context of such advances, you may need to obtain further services from 23andMe or from your physician or other health care provider.

You may learn information about yourself that you do not anticipate. This information may evoke strong emotions and has the potential to alter your life and worldview. You may discover things about yourself that trouble you and that you may not have the ability to control or change (e.g., your father is not genetically your father, surprising facts related to your ancestry, or that someone with your genotype may have a higher than average chance of developing a specific condition or disease). These outcomes could have social, legal, or economic implications.

The laboratory may not be able to process your sample, and the laboratory process may result in errors. The laboratory may not be able to process your sample if your saliva does not contain a sufficient volume of DNA, you do not provide enough saliva, or the results from processing do not meet our standards for accuracy. If the initial processing fails for any of these reasons, 23andMe will reprocess the same sample at no charge to the user. If the second attempt to process the same sample fails, 23andMe will offer to send another kit to the user to collect a second sample at no charge. If the user declines this option, the user is entitled solely and exclusively to a complete refund of the amount paid to 23andMe, less shipping and handling, provided that the user shall not resubmit another sample through a future purchase of the service. If the user opts to receive another sample collection kit and 23andMe's attempts to process the second sample are unsuccessful, 23andMe will not send additional sample collection kits and the user will be entitled solely and exclusively to a complete refund of the amount paid to 23andMe, less shipping and handling, provided the user shall not resubmit another sample through a future purchase of the service. If the user breaches this policy agreement and resubmits another sample through a future purchase of the service and processing is not successful, 23andMe will not offer to reprocess the sample or provide the user a refund. Even for processing that meets our high standards, a small, unknown fraction of the data generated during the laboratory process may be un-interpretable or incorrect (referred to as "Errors"). As this possibility is known in advance, users are not entitled to refunds where these Errors occur.

You should not change your health behaviors solely on the basis of information from 23andMe. Make sure to discuss your Genetic Information with a physician or other health care provider before you act upon the Genetic Information resulting from 23andMe Services. For most common diseases, the genes we know about are only responsible for a small fraction of the risk. There may be unknown genes, environmental factors, or lifestyle choices that are far more important predictors. If your data indicate that you are not at elevated genetic risk for a particular disease or condition, you should not feel that you are protected. The opposite is also true; if your data indicate you are at an elevated genetic risk for a particular disease or condition, it does not mean you will definitively develop the disease or condition. In either case, if you have concerns or questions about what you learn through 23andMe, you should contact your physician or other health care provider.

Genetic research is not comprehensive. While we measure many hundreds of thousands of data points from your DNA, only a small percentage of them are known to be related to human traits or health conditions. The research community is rapidly learning more about genetics, and an important mission of 23andMe is to conduct and contribute to this research. In addition, many ethnic groups are not included in genetic studies. Because interpretations provided in our service rely on these published studies, some interpretations may not apply to you. Future scientific research may change the interpretation of your DNA. In the future, the scientific community may show previous research to be incomplete or inaccurate.

Genetic Information you share with others could be used against your interests. You should be careful about sharing your Genetic Information with others. In the future, businesses or insurance companies may request Genetic Information. The Genetic Information Nondiscrimination Act was signed into law in the United States in 2008, and some, but not all, states and countries have laws that protect individuals with regard to their Genetic Information. You may want to consult a lawyer to understand the extent of legal protection of your Genetic Information before you share it with anybody.

Furthermore, Genetic Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Genetic Information that you share with family, friends or employers may be used against your interests. Even if you share Genetic Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Genetic Information about health conditions and you do not disclose this to them, this may be considered to be fraud.

23andMe Services are for research, informational, and educational use only. We do not provide medical advice. The Genetic Information provided by 23andMe is for research, informational, and educational use only. This means two things. First, many of the genetic discoveries that we report have not been clinically validated, and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing. Second, in order to expand and accelerate the understanding and practical application of genetic knowledge in health care, we invite all genotyped users to participate in 23andWe Research. Participation in such research is voluntary and based upon an IRB-approved consent document. As a result of the current state of genetic knowledge and understanding, our Services are for research, informational, and educational purposes only. The Services are not intended to be used by the customer for any diagnostic purpose and are not a substitute for professional medical advice. You should always seek the advice of your

physician or other health care provider with any questions you may have regarding diagnosis, cure, treatment, mitigation, or prevention of any disease or other medical condition or impairment or the status of your health.

23andMe does not recommend or endorse any specific course of action, resources, tests, physician or other health care providers, drugs, biologics, medical devices or other products, procedures, opinions, or other information that may be mentioned on our website. As explained on our website, 23andMe believes that (a) genetics is only part of the picture of any individual's state of being, (b) the state of the understanding of Genetic Information is rapidly evolving and at any given time we only comprehend part of the picture of the role of genetics, and (c) only a trained physician or other health care provider can assess your current state of health or disease, taking into account many factors, including in some cases your genetics as well as your current symptoms, if any. Reliance on any information provided by 23andMe, 23andMe employees, others appearing on our website at the invitation of 23andMe, or other visitors to our website is solely at your own risk.

While we are licensed in California as a clinical laboratory, not all jurisdictions require our Services to be subject to license. Therefore, we are not universally licensed by all state, federal, or international authorities for genetic testing conducted for health and disease-related purposes. In addition, there are certain jurisdictions in which we do not offer our Services because we do not have required licenses.

6. User Representations

By accessing 23andMe Services, you agree to, acknowledge, and represent as follows:

a. You understand that information you learn from 23andMe is not designed to diagnose, prevent, or treat any condition or disease or to ascertain the state of your health and that you understand that the 23andMe services are intended for research, informational, and educational purposes only. You acknowledge that 23andMe urges you to seek the advice of your physician or other health care provider if you have questions or concerns arising from your Genetic Information.
b. You give permission to 23andMe, its contractors, successors and assignees to perform genotyping services on the DNA extracted from your saliva sample and to disclose the results of analyses performed on your DNA to you and to others you specifically authorize.
c. You represent that you are eighteen (18) years of age or older if you are providing a saliva sample or accessing your Genetic Information.
d. You are guaranteeing that any sample you provide is your saliva; if you are agreeing to these TOS on behalf of a person for whom you have legal authorization, you are confirming that the sample provided will be the sample of that person.
e. If you are a customer outside the U.S. providing a saliva sample, you confirm that this act is not subject to any export ban or restriction in the country in which you reside.
f. You agree that any saliva sample you provide and all resulting data may be transferred and/or processed outside the country in which you reside.
g. You are warranting that you are not an insurance company or an employer attempting to obtain information about an insured person or an employee.
h. You are aware that some of the information you receive may provoke strong emotion.
i. You take responsibility for all possible consequences resulting from your sharing with others access to your Genetic Information and your Self-Reported Information.
j. You understand that all your Personal Information will be stored in 23andMe databases and will be processed in accordance with the 23andMe Privacy Statement.
k. Waiver of Property Rights: You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.

You agree that you have the authority, under the laws of the state or jurisdiction in which you reside, to provide these representations. In case of breach of any one of these representations 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof) and you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages arising out of the breach of the representation.

7. Account Creation, Customer Account, Password, and Security Obligations

In consideration of your use of the Services, you agree to: (a) provide true, accurate, current, and complete Registration Information about yourself as prompted by the Service; and (b) maintain and promptly update the Registration Information to keep it true, accurate, current, and complete. If you provide any Registration Information that is untrue, inaccurate, not current, or incomplete, or if 23andMe has a reasonable ground to suspect that such information is untrue, inaccurate, not current, or incomplete, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Service (or any portion thereof).

After you have purchased our Service, you will create a password and account designation. You are responsible for maintaining the confidentiality of the password and account, and are fully responsible for all activities that occur under your password or account. If you allow third parties to access 23andMe's website through your username and password, you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages, including attorney fees, arising out of claims or suits by such third parties based upon or relating to such access and use. You agree to (a) immediately notify 23andMe of any unauthorized use of your password or account or any other breach of security, and (b) ensure that you exit from your account at the end of each session. 23andMe cannot and will not be liable for any loss or damage arising from your failure to comply with this Section.

8. 23andMe Privacy Statement and Disclosure of Information

In order to use the Services, you must first acknowledge and agree to the Privacy Statement. You may not use the Services if you do not accept the Privacy Statement. You can acknowledge and agree to the Privacy Statement by (1) clicking to accept or agree to the Privacy Statement, where this option is made available to you by 23andMe for any Service; or by (2) actually using the Services.

You acknowledge and agree that 23andMe has the right to monitor any use of its systems by its personnel at any time and maintain copies documenting such monitoring. Our Privacy Statement sets forth the only expectations of privacy any individual should have in terms of usage of the 23andMe Services, website, or other systems. If you have given consent for your Genetic Information and Self-Reported Information to be used in 23andWe Research as described in the applicable Consent Document, we may include your information in the

Aggregated Genetic Information and Self-Reported Information we disclose to third parties for the purpose of publication in a peer-reviewed scientific journal. 23andMe may also include your information in Aggregated Genetic and Self-Reported Information disclosed to third-party non-profit and/or commercial research partners who will not publish that information in a peer-reviewed scientific journal. 23andMe will never release your individual-level Genetic Information and/or Self-Reported Information to any third party without asking for and receiving your explicit consent to do so, unless required by law. Further, you acknowledge and agree that 23andMe is free to preserve and disclose any and all Personal Information to law enforcement agencies or others if required to do so by law or in the good faith belief that such preservation or disclosure is reasonably necessary to: (a) comply with legal process (such as a judicial proceeding, court order, or government inquiry) or obligations that 23andMe may owe pursuant to ethical and other professional rules, laws, and regulations; (b) enforce the 23andMe TOS; (c) respond to claims that any content violates the rights of third parties; or (d) protect the rights, property, or personal safety of 23andMe, its employees, its users, its clients, and the public. In such event we will notify you through the contact information you have provided to us in advance, unless doing so would violate the law or a court order. You understand that the technical processing and transmission of the Services, including your Personal Information, may involve (a) transmissions over various networks; and (b) changes to conform and adapt to technical requirements of connecting networks, or devices. Finally, 23andMe may, in its sole discretion, restrict access to the website for any reason.

Please refer to our Privacy Statement to read about data protection related to your information. See our complete Privacy Statement here.

9. Limited License

You acknowledge that all User Content, whether publicly posted or privately transmitted, is the sole responsibility of the person from which such User Content originated. This means that you, and not 23andMe, are entirely responsible for all User Content that you upload, post, email, or otherwise transmit via the Service.

You acknowledge that the Services content presented to you as part of the Services, whether original 23andMe Services content or sponsored content within the Services, is protected by copyright and/or other intellectual property rights that are owned by 23andMe and/or the sponsors who provide that content to 23andMe (or by other persons or companies on their behalf). 23andMe grants you a Limited License to copy and distribute free of charge, for non-commercial purposes only, any of the Services content with the exception of content from "MD's Perspectives" in the "For the Experts" section of the website and any other content marked as not subject to this Limited License on the website, provided you: (i) provide the Services content as it appears on the 23andMe website with no changes including but not limited to presenting selections which might tend to misrepresent the substance of the Services content; (ii) include the following attribution on the first page of any materials you distribute: © 23andMe, Inc. 2008-2010. All rights reserved; distributed pursuant to a Limited License from 23andMe; (iii) agree you have no right to offer anyone else any further right with respect to this Services content. Aside from the Limited License provided in this paragraph, you may not modify, rent, lease, loan, sell, distribute, or create derivative works based on this Services content (either in whole or in part) unless you have been specifically told that you may do so by 23andMe or by the owners of that content, in a separate agreement.

10. Customer Conduct - Unlawful and Prohibited Use

As a condition of your use of the Services, you warrant to 23andMe that you will not use the Services for any purpose that is unlawful or prohibited by these terms, conditions, or notices. You may not use the Services in any manner that could damage, disable, overburden, or impair the Services or interfere with any other party's use and enjoyment of the Services. You may not obtain or attempt to obtain any materials or information through any means not intentionally made available or provided for through the Services. Furthermore you agree not to use the Services to: (1) upload, post, email, or otherwise transmit any material that is derogatory, defamatory, obscene, or offensive, such as slurs, epithets, or anything that might reasonably be construed as harassment or disparagement based on race, color, national origin, sex, sexual orientation, age, disability, religious or political beliefs, or other statutorily protected status; (2) impersonate any person or entity, including, but not limited to, anyone affiliated with 23andMe, or falsely state or otherwise misrepresent your affiliation with a person or entity; (3) add your own headers, forge headers, or otherwise manipulate identifiers in order to disguise the origin of any content transmitted through the Service; (4) "stalk" or otherwise harass another; (5) upload, post, email, or otherwise transmit any content that you do not have a right to transmit under any law or under contractual or fiduciary relationships (such as inside information, proprietary and confidential information learned or disclosed as part of employment relationships or under nondisclosure agreements); (6) download any file posted by another user of the Service that you know, or reasonably should know, cannot legally be distributed in such manner; (7) upload, post, email or otherwise transmit any content that infringes any patent, trademark, trade secret, copyright, or other proprietary rights ("Rights") of 23andMe or any other party; (8) harm minors in any way; (9) advertise or offer to sell or buy any goods or services for any business purpose, unless such area specifically allows such messages; (10) upload, post, email, or otherwise transmit any unsolicited or unauthorized advertising, promotional materials, "junk mail," "spam," "chain letters," "pyramid schemes," or any other form of solicitation, except in those areas that are designated for such purpose and only to the extent such content is authorized by law; (11) upload, post, email, or otherwise transmit any material that contains software viruses or any other computer code, files, or programs designed to interrupt, destroy, or limit the functionality of any computer software or hardware or telecommunications equipment; (12) interfere with or disrupt the Service or servers or networks connected to the Service, or disobey any requirements, procedures, policies, or regulations of networks connected to the Service; (13) violate these Terms of Service, any code of conduct or other guidelines which may be applicable for any particular area of the Service or have been communicated to you by anyone affiliated with 23andMe; or (14) intentionally or unintentionally violate any applicable local, state, national, or international law, or any regulations having the force of law.

You acknowledge and agree that you are solely responsible for (and that 23andMe has no responsibility to you or to any third party for) any breach of your obligations under the TOS and for the consequences (including any loss or damage which 23andMe may suffer) of any such breach. In case of breach of any one of these agreements 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof) and you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages arising out of the breach of the representation.

If you violate the terms of this Section and/or 23andMe has a reasonable ground to suspect that you have violated the terms of this Section, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Service (or any portion thereof).

11. Export Control and Applicable Laws and Regulations

Recognizing the global nature of the Internet, you agree to comply with all local rules regarding online conduct and acceptable content. Specifically, you agree 1) that providing your sample is not subject to any export ban or restriction in the country in which you reside, 2) that

your sample and data may be transferred and/or processed outside the country in which you reside, and 3) that you will comply with all applicable laws regarding the transmission of technical data exported from the United States or the country from which you access 23andMe's Services online.

12. Material Posted Through The Service

23andMe will not, at all times, control any of the User Content posted via the Service and, as such, does not guarantee the accuracy, integrity, or quality of such non-23andMe content. You understand that by using the Services, you may be exposed to content that is offensive, indecent, or objectionable. Under no circumstances will 23andMe be liable in any way for any non-23andMe content, including, but not limited to, any errors or omissions in any such content, or for any loss or damage of any kind incurred as a result of the use of any such content posted, emailed, or otherwise transmitted via the Services.

You acknowledge that 23andMe and its designees shall have the right (but not the obligation) in their sole discretion to pre-screen, review, filter, modify, refuse, or move any content that is available via the Services. Without limiting the foregoing, 23andMe and its designees shall have the right to remove any content that violates the TOS or is deemed by 23andMe, in its sole discretion, to be otherwise objectionable. You acknowledge and agree that you must evaluate, and bear all risks associated with, the use of any content, including any reliance on the accuracy, completeness, or usefulness of such content.

13. Material Provided to 23andMe - Your Proprietary Rights

User Content. 23andMe does not claim ownership of the User Content you provide to 23andMe (including feedback and suggestions) or post, upload, input, or submit to the Service. Unless otherwise specified, you retain copyright and any other rights you already hold over User Content that you create and submit, post, or display on or through the Services. However, by submitting, posting, or displaying User Content, you give 23andMe, its affiliated companies, sublicensees (including but not limited to sublicensees who avail themselves of the Limited License granted in Section 9 above) and successors and assigns a perpetual, irrevocable, worldwide, royalty-free, and non-exclusive license to reproduce, adapt, modify, translate, publish, publicly perform, publicly display, distribute, reproduce, edit, reformat, and create derivative works from any User Content that you submit, post, or display on or through the Services. You acknowledge and agree that this license includes a right for 23andMe to make such User Content available to other companies, organizations, or individuals with whom 23andMe has relationships, and to use such User Content in connection with the provision of those services.

You understand that 23andMe, in performing the required technical steps to provide the Services to our users, may (a) transmit or distribute your User Content over various public networks and in various media; and (b) make such changes to your content as are necessary to conform and adapt that content to the technical requirements of connecting networks, devices, services, or media. You acknowledge and agree that this license shall permit 23andMe to take these actions. You represent and warrant to 23andMe that you have all the rights, power, and authority necessary to grant the above license.

Genetic and/or Self-Reported Information. Disclosure of individual-level Genetic and/or Self-Reported Information to third parties will not occur without explicit consent, unless required by law. Note that 23andMe cannot control any further distribution of Genetic and/or Self-Reported Information that you share publicly on the 23andMe website. You acknowledge and agree that you are responsible for protecting and enforcing those rights and that 23andMe has no obligation to do so on your behalf.

Your saliva sample, once submitted to and analyzed by us, is processed in an irreversible manner and cannot be returned to you. See our website for more information on sample processing. Any Genetic Information derived from your saliva remains your information, subject to rights we retain as set forth in these TOS. You understand that you should not expect any financial benefit from 23andMe as a result of having your Genetic Information processed; made available to you; or, as provided in our Privacy Statement and Terms of Service, shared with or included in Aggregated Genetic and Self-Reported Information shared with research partners, including commercial partners.

Waiver of Property Rights. As stated above, you understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.

14. Indemnity

You agree to defend and hold 23andMe, and its subsidiaries, affiliates, officers, agents, contractors, partners, employees, successors, and assigns harmless from any claim, or demand, including reasonable attorneys' fees, made by any third party due to or arising out of User Content you submit, post to, or transmit through the Service; your use of the Service; your connection to the Service; your violation of the TOS; or your violation of any rights of another.

If you have submitted a saliva sample or otherwise provided your own Genetic Information, you will defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any liability arising out of the use or disclosure of any information obtained from genotyping your saliva sample and/or analyzing your Genetic Information, which is disclosed to you consistent with our Privacy Statement or results from any third-party add-ons to tools we provide. In addition, if you choose to provide your Genetic and/or Self-Reported Information to third parties - whether individuals to whom you facilitate access, intentionally or inadvertently, or to third parties for diagnostic or other purposes - you agree to defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any and all liability arising from such disclosure or use of your Genetic and/or Self-Reported Information.

15. No Resale of Service

Other than pursuant to the terms of the Limited License in Section 9 of this TOS or unless otherwise agreed in a separate agreement between you and 23andMe, you agree not to display, distribute, license, perform, publish, reproduce, duplicate, copy, create derivative works from, modify, sell, resell, exploit, transfer, or transmit for any commercial purposes, all or any portion of the Service, use of the Service, or access to the Service.

16. General Practices Regarding Use and Storage

You acknowledge that 23andMe may establish general practices and limits concerning use of the Services, including without limitation the maximum number of days that Personal Information and Services content will be retained by the Service, the maximum disk space that will be allotted on 23andMe's servers on your behalf, and the maximum number of times (and the maximum duration for which) you may access

the Services in a given period of time. You acknowledge and agree that 23andMe has no responsibility or liability for the deletion of or failure to store any messages, other communications, or other content maintained or transmitted by the Services; or for the loss of Genetic Information due to malfunction or destruction of data servers or other catastrophic events. You further acknowledge that 23andMe reserves the right to change these general practices and limits in its sole discretion.

17. Modifications to Service

23andMe reserves the right at any time and from time to time to modify or discontinue, temporarily or permanently, the Services (or any part thereof) with or without notice. You acknowledge and agree that 23andMe shall not be liable to you or to any third party for any modification, suspension, or discontinuance of the Services.

The Software that you use may from time to time automatically download and install updates from 23andMe. These updates are designed to improve, enhance, and further develop the Services and may take the form of bug fixes, enhanced functions, new software modules, and completely new versions. You agree to receive such updates (and permit 23andMe to deliver these to you) as part of your use of the Services.

You acknowledge that 23andMe may offer different or additional technologies to collect and/or interpret Genetic Information in the future and that your initial purchase of the Service does not entitle you to any different or additional technologies for collection or interpretation of your Genetic Information without fee, and that you will have to pay additional fees in order to have your Genetic Information collected, processed, and/or interpreted using any future or additional technologies.

18. Termination

The TOS will continue to apply until terminated by either you or 23andMe as set out in this Section.

If you want to terminate your legal agreement with 23andMe, you may do so by notifying 23andMe at any time in writing, which will entail closing your accounts for all of the Services that you use. Your notice should be sent, in writing, to 23andMe's address, which is set out at the beginning of the TOS.

23andMe may at any time, terminate its legal agreement with you (and in conjunction therewith, your password and account(s)) if: (1) you have breached any provision of the TOS (or have acted in manner which shows that you do not intend to, or are unable to comply with, the provisions of the TOS); (2) 23andMe is required to do so by law (for example, where the provision of the Services to you is, or becomes, unlawful); (3) the partner with whom 23andMe offered the Services to you has terminated its relationship with 23andMe or ceased to offer the Services to you; (4) 23andMe is transitioning to no longer providing the Services to users in the country or state in which you reside or from which you use the Services; or (5) the provision of the Services to you by 23andMe is, in 23andMe's opinion, no longer commercially viable.

Any suspected fraudulent, abusive, or illegal activity that may be grounds for termination of your use of the Services may be referred to appropriate law enforcement authorities. You acknowledge and agree that 23andMe shall not be liable to you or any third party for any termination of your access to the Services.

19. Survival of Terms

When the TOS come to an end, all of the legal rights, obligations, and liabilities that you and 23andMe have benefited from, been subject to (or which have accrued over time while the TOS have been in force) or which are expressed to continue indefinitely, shall be unaffected by this cessation, and the provisions of sections 1.(Definitions); 2.(Acceptance of Terms); 3.(Prerequisites); 4.(Description of the Services); 5. (Risks and Considerations Regarding 23andMe Services); 6.(Representations); 7.(Account Creation, Customer Account, Password and Security Obligations); 8.(23andMe Privacy Statement); 10.(Customer Conduct - Unlawful and Prohibited Use); 11.(Export Control and Applicable Laws and Regulations); 12.(Material Posted through the Service); 13.(Material Provided to 23andMe - Your Proprietary Rights); 14.(Indemnity); 15.(No resale of Services);18.(Termination); 19.(Survival of Terms); 20.(Dealings with Information Providers and Listed Resources); 21.(Hyperlinks and 23andMe Website); 22.(23andMe Proprietary Rights); 23.(DISCLAIMER OF WARRANTIES); 24. (LIMITATION OF LIABILITY); 25.(Notice); 27.(Violation or Suspected Violation of TOS); and 28.(Miscellaneous) shall continue to apply to such rights, obligations, and liabilities indefinitely.

20. Dealings with Information Providers and Listed Resources

Your correspondence or business dealings with-or participation in promotions of-information providers, vendors, and/or resources found on or through the Service, including payment and delivery of related goods or services, and any other terms, conditions, warranties, or representations associated with such dealings, are solely between you and such information provider or resource. You acknowledge and agree that 23andMe shall not be responsible or liable for any loss or damage of any sort incurred as the result of any such dealings or as the result of the presence of such information provider or resources on the Service.

21. Hyperlinks and the 23andMe Website

The Service provides, and third parties may provide, links to other sites and resources on the Internet. Because 23andMe has no control over such sites and resources, you acknowledge and agree that 23andMe is not responsible for the availability of such external sites or resources, and does not endorse and is not responsible or liable for any content, advertising, products, or other materials on or available from such sites or resources. You further acknowledge and agree that 23andMe shall not be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with use of or reliance on any such content, goods, or services available on or through any such hyperlinked site or resource.

22. 23andMe's Proprietary Rights

You acknowledge and agree that 23andMe (or 23andMe's licensors, as applicable) own all legal right, title, and interest in and to the Services, including any intellectual property rights which subsist in the Services (whether those rights happen to be registered or not, and wherever in the world those rights may exist). You further acknowledge that the Services may contain information which is designated confidential by 23andMe and that you shall not disclose such information without 23andMe's prior written consent.

You further acknowledge and agree that the Services and any necessary software used in connection with the Services ("Software") contain proprietary and confidential information that is protected by applicable intellectual property and other laws. You further acknowledge and

agree that information presented to you through the Services or sponsors is protected by copyrights, trademarks, service marks, patents, or other proprietary rights and laws. Except as expressly authorized by 23andMe, you agree not to-and not to permit anyone else to-modify, rent, lease, loan, sell, distribute, or create derivative works of, reverse engineer, decompile, or otherwise attempt to extract the source code of the Services or Software or any part thereof, in whole or in part. Software, if any, that is made available to download from the Services, excluding software that may be made available by end-users through the Services, is the copyrighted work of 23andMe and/or its suppliers. Your use of the Software is governed by the terms of the end user license agreement, if any, which accompanies or is included with the Software ("License Agreement"). You may not install or use any Software that is accompanied by or includes a License Agreement unless you first agree to the License Agreement terms.

23andMe, Inc., 23andMe, and other 23andMe logos and product and service names are trademarks of 23andMe and these marks together with any other 23andMe trade names, service marks, logos, domain names, and other distinctive brand features are the **"23andMe Marks"**. Unless you have agreed otherwise in writing with 23andMe, other than through the Limited License in Section 9, nothing in the TOS gives you a right to use any 23andMe Marks and you agree not to display, or use in any manner, 23andMe Marks.

You agree that you shall not remove, obscure, or alter any proprietary rights notices (including copyright and trade mark notices) that may be affixed to or contained within the Services.

Unless you have been expressly authorized to do so in writing by 23andMe, you agree that in using the Services, you will not use any trade mark, service mark, trade name, logo of any company or organization in a way that is likely or intended to cause confusion about the owner or authorized user of such marks, names, or logos.

For any Software not accompanied by a License Agreement, 23andMe grants you a personal, non-transferable, and non-exclusive right and license to use the object code of its Software on a single computer. You may not (and may not allow any third party to) copy, modify, create a derivative work of, reverse engineer, reverse assemble, or otherwise attempt to discover any source code, sell, assign, sublicense, grant a security interest in, or otherwise transfer any right in the Software unless this is expressly permitted or required by law, or unless you have been specifically told that you may do so by 23andMe, in writing. This license is for the sole purpose of enabling you to use and enjoy the benefit of the Services as provided by 23andMe, in the manner permitted by the TOS. Unless 23andMe has given you specific written permission to do so, you may not assign (or grant a sublicense of) your rights to use the Software, grant a security interest in or over your rights to use the Software, or otherwise transfer any part of your rights to use the Software. You agree not to modify the Software in any manner or form, or to use modified versions of the Software, including (without limitation) for the purpose of obtaining unauthorized access to the Service. You agree not to access the Service by any means other than through the interface that is provided by 23andMe for use in accessing the Service. Any rights not expressly granted herein are reserved.

23. Disclaimer of Warranties

YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT: (1) YOUR USE OF THE SERVICES ARE AT YOUR SOLE RISK. THE SERVICES ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. 23ANDME EXPRESSLY DISCLAIMS ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. (2) 23ANDME MAKES NO WARRANTY THAT (a) THE SERVICES WILL MEET YOUR REQUIREMENTS; (b) THE SERVICES WILL BE UNINTERRUPTED, TIMELY, UNFAILINGLY SECURE, OR ERROR-FREE; (c) THE RESULTS THAT MAY BE OBTAINED FROM THE USE OF THE SERVICES WILL BE ACCURATE OR RELIABLE; (d) THE QUALITY OF ANY PRODUCTS, SERVICES, INFORMATION, OR OTHER MATERIAL PURCHASED OR OBTAINED BY YOU THROUGH THE SERVICES WILL MEET YOUR EXPECTATIONS AND (e) ANY ERRORS IN THE SOFTWARE WILL BE CORRECTED. (3) ANY MATERIAL DOWNLOADED OR OTHERWISE OBTAINED THROUGH THE USE OF THE SERVICES IS DONE AT YOUR OWN DISCRETION AND RISK AND THAT YOU WILL BE SOLELY RESPONSIBLE FOR ANY DAMAGE TO YOUR COMPUTER SYSTEM OR LOSS OF DATA THAT RESULTS FROM THE DOWNLOAD OF ANY SUCH MATERIAL. (4) NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED BY YOU FROM 23ANDME OR THROUGH OR FROM THE SERVICES SHALL CREATE ANY WARRANTY NOT EXPRESSLY STATED IN THE TOS. (5) YOU SHOULD ALWAYS USE CAUTION WHEN GIVING OUT ANY PERSONALLY IDENTIFYING INFORMATION ABOUT YOURSELF OR THOSE FOR WHOM YOU HAVE LEGAL AUTHORITY. 23ANDME DOES NOT CONTROL OR ENDORSE ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES AND, THEREFORE, 23ANDME SPECIFICALLY DISCLAIMS ANY LIABILITY WITH REGARD TO ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES.

24. Limitation of Liability

WITHIN THE LIMITS ALLOWED BY APPLICABLE LAWS, YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT 23ANDME SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, GOODWILL, USE, DATA OR OTHER INTANGIBLE LOSSES (EVEN IF 23ANDME HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), RESULTING FROM: (a) THE USE OR THE INABILITY TO USE THE SERVICES; (b) ANY ACTION YOU TAKE BASED ON THE INFORMATION YOU RECEIVE IN THROUGH OR FROM THE SERVICES, (v) YOUR FAILURE TO KEEP YOUR PASSWORD OR ACCOUNT DETAILS SECURE AND CONFIDENTIAL, (d) THE COST OF PROCUREMENT OF SUBSTITUTE GOODS AND SERVICES RESULTING FROM ANY GOODS, DATA, INFORMATION, OR SERVICES PURCHASED OR OBTAINED OR MESSAGES RECEIVED OR TRANSACTIONS ENTERED INTO THROUGH OR FROM THE SERVICES; (e) UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OR DATA; (f) THE IMPROPER AUTHORIZATION FOR THE SERVICES BY SOMEONE CLAIMING SUCH AUTHORITY; or (g) STATEMENTS OR CONDUCT OF ANY THIRD PARTY ON THE SERVICES.

25. Notice

Notices to you may be made via either email or regular mail. 23andMe may also provide notices of changes to the TOS or other matters by displaying notices or links to notices to you generally on or through the Services.

Official notices related to this TOS must be sent to us at: 23andMe, Inc.
ATTN: General Counsel
1390 Shorebird Way
Mountain View, CA 94043

Any notices that you provide without compliance with this section on Notices shall have no legal effect.

26. Changes to the Terms of Service

23andMe may make changes to the TOS from time to time. When these changes are made, 23andMe will make a new copy of the TOS available on its website and any new additional terms will be made available to you from within, or through, the affected Services.

You acknowledge and agree that if you use the Services after the date on which the TOS have changed, 23andMe will treat your use as acceptance of the updated TOS.

27. Violation or Suspected Violation of Terms of Service

If you violate the terms of these TOS and/or 23andMe has a reasonable ground to suspect that you have violated the terms of these TOS, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof).

28. Miscellaneous

a. **Entire Agreement.** The TOS constitute the entire agreement between you and 23andMe and govern your use of the Services, superseding any prior agreements between you and 23andMe on this subject. You also may be subject to additional terms and conditions that may apply when you use affiliate services, third-party content, or third-party software
b. **Applicable law and arbitration.** Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with 23andMe arising out of or relating to the Agreement (**"Disputes"**) shall be governed by California law regardless of your country of origin or where you access 23andMe, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in San Francisco, California, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.
c. **Waiver.** The failure of 23andMe to exercise or enforce any right or provision of the TOS shall not constitute a waiver of such right or provision. If any provision of the TOS is found by a court of competent jurisdiction to be invalid, the parties nevertheless agree that the court should endeavor to give effect to the parties' intentions as reflected in the provision, and the other provisions of the TOS remain in full force and effect.
d. **Term for cause of action.** You agree that regardless of any statute or law to the contrary, any claim or cause of action arising out of or related to use of the Services or the TOS must be filed within one (1) year after such claim or cause of action arose or be forever barred.
e. **Admissibility of printed version.** A printed version of this agreement and of any notice given in electronic form shall be admissible in judicial or administrative proceedings based upon or relating to this agreement to the same extent and subject to the same conditions as other business documents and records originally generated and maintained in printed form.
f. **Section titles.** The section titles in the TOS are for convenience only and have no legal or contractual effect.
g. **Severability Clause.** If any portion of these TOS is found to be unenforceable, the remaining portion will remain in full force and effect.
h. **Amendments.** We reserve the right to modify, supplement or replace the terms of the Agreement, effective upon posting at www.23andMe.com or notifying you otherwise. If you do not want to agree to changes to the Agreement, you can terminate the Agreement at any time per Section 18 (Termination).
i. **Assignment:** You may not assign or delegate any rights or obligations under the Agreement. Any purported assignment and delegation shall be ineffective. We may freely assign or delegate all rights and obligations under the Agreement, fully or partially without notice to you. We may also substitute, by way of unilateral novation, effective upon notice to you, 23andMe for any third party that assumes our rights and obligations under this Agreement.

Previous version of this document

Attachment C

considerations

23andMe believes there is great promise in helping people access and understand their genetic information, but the advent of personal genetics is not without risk. To help you understand the benefits and potential drawbacks of accessing your own genetic information, we present a few issues you should consider before joining 23andMe.

You may learn surprising things about yourself.

There is a chance you could be surprised by what you learn about your genome. For example, you could discover that your father is not your biological parent. You could learn that individuals with your genetic profile are at increased risk of developing a currently incurable disease. You might learn something unexpected about your ancestry. In certain cases, these discoveries could have social, legal or economic implications.

The laboratory process can result in errors.

Our samples are processed by a federally licensed laboratory using processes that are designed to deliver the highest quality data possible. However, a small, unknown fraction of the data generated during the laboratory process may be inconclusive or incorrect.

Genetics is not destiny.

Your genes are only one factor among many that influence who you are. It is important to recognize that your diet, lifestyle, environment and even luck can be equally or more important than genes in determining your future.

It is also important to understand that 23andMe assesses the genetic chances of developing a given disease or condition by consulting scientific reports that associate certain genetic profiles with increased or decreased risk and comparing your results to them. Though we are confident in the quality of both our laboratory procedures and the scientific research we choose to include in our analyses, these aspects are currently the only information our service takes into account. That means we cannot and do not diagnose diseases or medical conditions, provide medical advice or otherwise assess your health. You should always contact your physician, a genetic counselor or other professional if you have any questions or concerns about what you learn through 23andMe.

Genetic research is not yet complete.

Studies associating genes with traits and conditions have not yet been performed in all ethnic groups. Because we can only present the results of whatever studies have been done, what you learn may not apply to someone with your ethnic background. However, 23andMe could overcome this obstacle over time–if enough people of various ethnic backgrounds are willing to anonymously share their genetic data and basic information about their traits and medical conditions, we may be able to fill in some of those gaps.

Future scientific research may change the interpretation of your DNA.

It is possible that future research may render current information incomplete or inaccurate. The good news is that significant progress is being made in the field of genetic association research, and we will keep you abreast of the latest developments.

You should consider how others may use your genetic data before sharing it.

Purchasing 23andMe's service does not require you to share your genetic information with anyone, but it does offer you the option of making your data available to others. Before you decide to share your information, you should consider how those parties might use your genetic data now and in the future. For example, a motivated party with whom you share your data might be able to use our tools to discover things that you had not anticipated. It is also possible that future scientific research will shed new light on data you reveal today, giving it new significance that you would rather not share with others.

Please see our policy forum if you would like to learn more about these important considerations.

Attachment D

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Core Values
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Board of Directors
Editorial Advisors
Scientific Advisory Board

news

23andMe press release

23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers

MOUNTAIN VIEW, CA – June 3, 2010 – 23andMe, Inc., a leading personal genetics company, has engaged Informed Medical Decisions, Inc. (InformedDNA), a nationwide network of board-certified genetics experts, to offer independent genetic counseling services to new and existing customers of its Personal Genome Service™.

"This new initiative with InformedDNA means that 23andMe customers now have the option to talk about their results with a board-certified genetic counselor who has been specially trained in 23andMe's unique reports and processes," said Anne Wojcicki, 23andMe President and Co-Founder.

"We chose to work with InformedDNA because they are a leading national independent provider of genetic counseling services," stated Wojcicki. "We wanted to ensure that the information our customers receive is completely objective."

23andMe customers interested in talking with a genetic counselor from InformedDNA can choose from two levels of service. For those with general questions related to their 23andMe results, an informational Personal Genome Service (PGS) is available. Customers who want a counselor to conduct a more thorough review of their family and medical histories, and those whose results show that they carry variants with potentially serious implications, can choose Comprehensive Clinical Genetic Counseling. Determining whether the Comprehensive Clinical Genetic Counseling option is appropriate is based on national clinical guidelines for genetic counseling referral.

23andMe customers who choose to utilize the services of InformedDNA will connect with a genetic counselor by phone. Convenient appointments are available seven days a week and can be scheduled online or by calling a dedicated toll-free phone line. InformedDNA Patient Care Coordinators are available to assist customers in choosing the level of service that is right for them. All information will be kept strictly confidential. A guide to the pricing for 23andMe customers who wish to utilize the genetic counseling services is listed on InformedDNA's website.

"Informed Medical Decisions is pleased to be working with 23andMe to expand access to genetics experts, especially for people who know of or suspect they may be at risk for hereditary disease. We salute 23andMe for offering customers convenient access to our genetic counselors," said David Patrick Nixon, Informed Medical Decisions Chief Executive Officer.

About 23andMe

23andMe, Inc. is a leading personal genetics company dedicated to helping individuals understand their own genetic information through DNA analysis technologies and web-based interactive tools. The company's Personal Genome Service™ enables individuals to gain deeper insights into their ancestry and inherited traits. The vision for 23andMe is to personalize healthcare by making and supporting meaningful discoveries through genetic research. 23andMe, Inc., was founded in 2006, and the company is advised by a group of renowned experts in the fields of human genetics, bioinformatics and computer science. Its investors include Genentech, Inc., Google Inc. (NASDAQ: GOOG) and New Enterprise Associates. More information is available at www.23andme.com.

About Informed Medical Decisions, Inc. (InformedDNA)

InformedDNA includes the largest independent network of genetic counselors and is the only national provider whose services are a covered benefit for most individuals with commercial health insurance. Its pioneering telephonic service delivery model removes barriers to care (geography, language, cultural and clinical specialty) for patients and has been recognized by the Institute of Medicine and Surgeons Generals' National Call to Action on Cancer for innovations and clinical excellence.

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Press Releases

June 24, 2010 23andMe Makes New Discoveries in Genetics Using Novel, Web-based, Participant-driven Methods
June 3, 2010 23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers
October 13, 2009 23andMe Tests NFL Players' DNA for Athletic Genetic Factors
April 27, 2009 23andMe and Palomar Pomerado Health Partner to Give PPH Members Access to Their Genetic Information
March 31, 2009 23andMe Launches Free Online Community For Moms and Moms-to-Be
March 12, 2009 23andMe Launches Parkinson's Disease Genetics Initiative
January 28, 2009 23andMe and mondoBIOTECH Partner to Advance Research of Rare Diseases
December 18, 2008 Silicon Valley Veterans Sarah Imbach and Larry Tesler Join 23andMe Management Team
December 8, 2008 23andMe Announces Holiday Season Multi-Pack Discount
October 30, 2008 TIME Magazine Names 23andMe's Personal Genome Service 2008 Invention of the Year
October 2, 2008 23andMe Announces Breast Cancer Initiative
September 9, 2008 23andMe Democratizes Personal Genetics
September 9, 2008 23andMe and Ancestry.com Partner to Extend Access to Genetic Ancestry Expertise
May 29, 2008 23andMe Launches Consumer-Enabled Research Program to Actively Engage Individuals in Genetics Research
May 14, 2008 23andMe and The Parkinson's Institute Announce Initiative to Advance Parkinson's Disease Research
January 22, 2008 23andMe Launches Web-Based Personal Genome Service™ Outside U.S.
November 29, 2007 23andMe Selected as a 2008 Technology Pioneer by the World Economic Forum
November 19, 2007 23andMe Launches Web-Based Service Empowering Individuals to Access and Understand Their Own Genetic Information
November 16, 2007 23andMe to Hold Webcast Media Briefing
May 22, 2007 23andMe, Inc. Completes Series A Financing

Attachment E

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June 28, 2010

Michael J. Madigan
(202) 339-8523
mmadigan@orrick.com

Hon. Henry A. Waxman, Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Hon. Joe Barton, Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Hon. Bart Stupak, Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515-6115

Hon. Michael C. Burgess, Ranking Member
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: June 14, 2010 letter request to Anne Wojcicki, President, 23andMe, Inc.

Dear Chairman Waxman, Ranking Member Barton, Chairman Stupak and Ranking Member Burgess:

On June 14, 2010, you sent a letter request to Anne Wojcicki, President of 23andMe, Inc. ("23andMe" or "the Company"), seeking information related to a June 8, 2010 announcement by the Company relating to a number of customer DNA samples. While we are in the process of producing responsive documents, the Company would like to take this opportunity to explain the incident. At the outset, we understand that a representative of the laboratory processing and analysis company that 23andMe uses will meet with you this week and will certainly be in the best position to discuss the issues that occurred within their facility. Our description of events at the laboratory is limited to 23andMe's own understanding of what happened there.

I. How 23andMe's Collection of Customer DNA Samples and NGI's Processing and Analysis Operate

Preliminarily, we thought it would help to provide a step-by-step explanation of how 23andMe operates with respect to the collection of customer DNA samples and their processing and analysis by the Company's third-party laboratory vendor, the National Genetics Institute ("NGI") a wholly owned subsidiary of the Laboratory Corporation of America.

First, customers visit the 23andMe website and purchase one of three products for personalized genetic testing. 23andMe then sends to each customer a kit to collect a DNA sample, including a vial for saliva marked with a unique barcode, from which customer DNA will be

extracted and analyzed by NGI. The customer deposits a sample of saliva in the vial and then sends it directly to NGI. The Company uses the unique barcode on each saliva collection vial to track and distinguish each customer's unique data while maintaining customer privacy.

NGI is a Clinical Laboratory Improvement Amendments Program-certified laboratory that provides advanced clinical genetics testing services for blood screening, medical testing, and clinical research. Licensed as a clinical laboratory provider by both state and federal agencies, NGI participates in a number of approved quality control programs, and holds active Biologics Licenses from the U.S. Food and Drug Administration for screening of plasma for blood borne infectious agents. It also provides advanced genetic testing services to physicians, hospitals, and clinics and has supported numerous pharmaceutical and biotechnology companies in the clinical development of new infectious disease and oncology therapies. (see http://www.ngi.com/services/index.asp). We understand NGI complies with strict professional, regulatory, and corporate quality-assurance standards. 23andMe employees and consultants do not participate in the processing and analysis of data at NGI, although we rely on the data returned.

Upon receipt of the saliva samples, NGI logs them by their assigned bar codes into NGI's system, and then processes them through "amplification," extracting the customers' DNA from their saliva samples. Each customer's DNA is then placed by pipette into an assigned slot contained on a well plate. The well plates used by NGI for testing of 23andMe customer samples are 5"x7", and contain 96 slots to allow for the processing of up to 96 customer DNA samples per plate. These well plates are then inserted into Illumina-platform equipment for analysis of nearly 600,000 data points that 23andMe provides to its customers.

After NGI completes the analysis, the collected data for each sample is linked to its accompanying bar code, and NGI electronically sends the data encrypted to 23andMe through a secure FTP site. A single electronic file contains the data from one well plate. Upon receiving this data, 23andMe matches each barcode to the customer it belongs to, and then uploads the data from each barcode to the customer's individual account. Finally, 23andMe sends emails to its customers notifying them that their data are loaded and ready for viewing.

II. Factual Background of the June 2010 Incident

Summary

In brief, the June 2010 incident was caused by the human error of one of NGI's certified technicians accidentally and wrongly inverting one well plate, which contained 96 customer DNA samples, nine of which failed processing by 180 degrees. This led to the Company's receipt of incorrect results, which were then transmitted to customers. However, 23andMe responded rapidly to the problem, advised consumers of the problem, removed the inaccurate results in less than 24 hours, and provided those impacted with their correct results within six (6) days. While 23andMe

takes the incident seriously, the Company rapidly resolved it. Since the incident, both 23andMe and NGI have further strengthened their quality control systems to avoid any further such problems.

Detailed Account

The aforementioned inversion of the well plate by 180 degrees caused NGI's computer to assign DNA information to incorrect barcodes, as the slots were assigned to barcodes in the computer before plate insertion. I note that the plate inversion could have happened in any such lab for any such tests coming from any hospital, doctor's office, or other NGI client – it was not a problem uniquely related to 23andMe samples. Unfortunately, NGI did not detect the error before it transmitted the erroneous electronic data file from the inverted plate to 23andMe. The Company received the NGI-generated, faulty data and uploaded it to each customer's individual account and emailed those customers that their data was available. Customers received these emails between 6 and 9 p.m. on the evening of June 1.

Early in the morning of June 2, 23andMe's Director of Engineering, Alex Khomenko, checked his email and was alerted that several 23andMe customers had apparently received inaccurate genetic reports. For example, in at least one instance, a customer had received genetic data indicating that the customer was the wrong sex. That same morning, Mr. Khomenko contacted the Company's Customer Service Manager, Michelle Klucsor, who said she had received similar customer complaints via email.

To identify what happened, Mr. Khomenko ran a program covering 100% of the samples received from NGI on June 1. This program provided the names (which the customers provided when signing up with 23andMe) and sex (which the lab identified in its DNA analysis) of these customers. He then compared a customer's name against the lab-identified sex of the customer. He noticed that, in some instances, the gender of a customer's name (for example, "Sarah") did not match the sex (for example, "male") contained in the lab report. He compiled a list of all such inconsistencies. Mr. Khomenko then reviewed the original electronic files sent from NGI on June 1, 2010 and determined that all of the inconsistencies stemmed from a single electronic file, and, thus, he concluded, from one well plate.

As Mr. Khomenko conducted his investigation, 23andMe alerted NGI of the error. NGI also conducted its own investigation. Around 1 pm on June 2, 2010, 23andMe concluded that the data from the single file containing 87 customer data sets contained inaccuracies and began the process of removing this data from the accompanying accounts. During this period, 23andMe continued discussions with NGI. At approximately 4 pm on June 2, 2010 – less than 24 hours after customers had received the incorrect data -- 23andMe deleted the erroneous data from the affected customers' databases and sent emails to each affected customer alerting them of the error.

On June 5, NGI confirmed that its investigation had concluded that the issue stemmed from an error on a single well plate. NGI's investigation showed that the well plate had been inverted, causing the inaccurate customer data. NGI had reprocessed the data of all impacted customers while its investigation was ongoing. NGI re-ran the entire plate from both the amplified DNA samples and the original saliva samples provided by the customers. In doing so, NGI was able to confirm the accuracy of the updated data. 23andMe was able to upload correct reports into the affected customers' accounts on June 8, 2010.

III. Steps Taken by 23andMe and NGI to Ensure No Future Errors

Since this incident, NGI has informed 23andMe that NGI has taken steps to help ensure that such errors do not recur. Specifically, 23andMe understands that NGI has modified the physical shape of its well plates to prevent them from being inverted in the machine that conducts the analysis. Attached please find a photograph of the old well plate and one of the newly-designed well plates that are now in use.

For its part, 23andMe has implemented improved quality-control procedures to double-check the accuracy of NGI's returned lab results before providing them to customers. For the period of June 8 through June 23, 23andMe cross-referenced a customer's name (which 23andMe predicts to be either male or female based on traditional name use) with the customer's sex information pulled from lab data. Doing so allowed 23andMe to identify potential errors, where the gender of a customer's name is inconsistent with lab-identified sex data for that customer.

Starting June 24, 23andMe implemented a similar quality check with additional data. As of June 10, 2010, 23andMe has been collecting customer date of birth and sex information pursuant to requirements that NGI is following. 23andMe's new process cross-references this customer-provided sex data with that generated by the lab data. Potential errors will be flagged where there are inconsistencies.

We look forward to speaking with you further about this issue. If you have any questions in the meantime, please call me at (202) 339-8523.

Sincerely,

Michael J. Madigan
Joshua P. Galper
Stephanie Maya Cowles

Attachment F

FDA U.S. Food and Drug Administration

Medical Devices

Home Use Tests

Home use tests allow you to test for some diseases or conditions at home. These tests are cost-effective, quick, and confidential. Home use tests can help:

- detect possible health conditions when you have no symptoms, so that you can get early treatment and lower your chance of developing later complications (i.e. cholesterol testing, hepatitis testing).
- detect specific conditions when there are no signs so that you can take immediate action (i.e. pregnancy testing).
- monitor conditions to allow frequent changes in treatment (i.e. glucose testing to monitor blood sugar levels in diabetes).

Despite the benefits of home testing, you should take precautions when using home-use tests. Home use tests are intended to help you with your health care, but they should not replace periodic visits to your doctor. Many times, you should talk to your doctor even if you get normal test results. Most tests are best evaluated together with your medical history, a physical exam, and other testing. Always see your doctor if you are feeling sick, are worried about a possible medical condition, or if the test instructions recommend you do so.

Approvals

- Find All FDA-Approved Home and Lab Tests[1]

Related Links

- How You Can Get the Best Results With Home Use Tests[2]
- How You Can Know If FDA Regulates an Over-The-Counter Test[3]

Links on this page:

1. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LabTest/ucm126079.htm
2. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/ucm125664.htm
3. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/ucm125666.htm